EPA/ACC Technical Workshop for the Voluntary Children's Chemical Evaluation Program

Exposure Assessment Example for Chemical C

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The Exposure Assessment

- Exposure Pathways
- Affected Populations
- Monitoring studies
- Modeling
- Data Needs
  - Were all potential pathways examined?
  - If not, future research needs

Monitoring Data

- Concentrations of Chemical C in Breast milk of Women in a Manufacturing Plant
- Worker Inhalation at a Processing Facility
- Residential Crack and Crevice Application
- Residential Air Monitoring after Crack and Crevice Application
- Department of Defense National Groundwater Study
- Ongoing Studies

Monitoring Study: Breast Milk in Chemical C Workers

$$APDR = C \times CR / BW$$

where:

APDR	=	acute potential dose rate (mg/kg/day);
C	=	concentration of Chemical C in Breast Milk (0.03 to 0.26 mg/L);
CR	=	consumption rate (0.7 L/day); and
BW	=	body weight (7.2 kg).

Monitoring Study: Breast Milk in Chemical C Workers

- Limitations:
  - Only 4 workers in study
  - External exposures not controlled
  - Demographic factors not addressed
  - Location of house in relation to plant not known
  - Workers performed different jobs

Monitoring Study: Crack and Crevice Postapplication Exposure

- Study Objective: Estimate potential inhalation exposures to Chemical C among children residing in homes where Pest-X is used for crack and crevice treatment

Monitoring Study: Crack and Crevice Postapplication Exposure

- Study Results: The study used the detection limit for Chemical C in air to calculate inhalation exposures because no measurable concentrations of Chemical C were observed in air.

Monitoring Study: Crack and Crevice Postapplication Exposure

- Applicability of Study
  - Study objectives
  - Relevant to Population of Concern [Children]?
- Quality of study
    - Quality & quantity of data
    - Study methodology

Monitoring Study: Crack and Crevice Postapplication Exposure

- Study/Data limitations:
  - Limited to 5 homes in California.
  - Air monitoring below detectable levels: had to use LOD for exposure estimates
  - QA/QC measures taken: recoveries > 90%

Monitoring Study: Crack and Crevice Postapplication Exposure

ADD = C x IR / BW

Where:

ADD	=	average daily dose (mg/kg/day);
C	=	concentration of Chemical C in air (<0.006 Fg/m^3);
IR	=	inhalation rate (8.3 m^3/day); and
BW	=	body weight (15 kg).

ADD = <0.003 Fg/kg/day

Monitoring Study: Groundwater

- Purpose: to examine levels of a variety of chemicals in the nation's groundwater
- Results:
  - Chemical C was detected in 486 of the 563 groundwater samples analyzed
  - The detection limit was 0.1 Fg/L;
  - The mean concentration was 0.25 Fg/L
  - The range of detected values was 0.11 to 0.56 Fg/L.

Monitoring Study: Groundwater

$$APDR = C \times IR / BW$$

where:

APDR = acute potential dose rate daily dose (Fg/kg/day);

C = mean concentration of Chemical C in groundwater (0.25 Fg/L);

IR = ingestion rate of water (1 L/day);

BW = body weight (15 kg).

Modeling Exposure

- Use of ISCLT to Model Dispersion of Fugitive Emissions of Chemical C from Manufacturing Plant
- Dermal and Hand-to-mouth Exposure Among Children in Pest-X-Treated Indoor Environments
- Aggregate Exposure to Chemical C Among Children
- Ongoing Studies

Modeling Exposure

- Model Selection
  - Computerized model or other, i.e., SOP
  - Validation/Peer Review Status of Model
    - Internal or external validation
- Model Inputs
  - Measured or estimated
  - Conservative or typical values
- Availability of Model
  - Open or proprietary format

Modeling Fugitive Plant Emissions Exposure

- ISCLT Model from PC GEMS (US EPA)
- Single Site Modeled:
  - 100 lbs / year
  - 24 hr x 365 days
  - max air concentration 4.74×10^{-4} Fg/m^3
  - max dose 1.36×10^{-7} mg/kg/day

Example: Modeling Indoor Crack and Crevice Treatment: **Dermal and Hand-to-Mouth Exposures**

- Description of Exposure Scenario
- Results
- Uncertainty
  - Basis of inputs
    - population surveys
    - individual studies
    - market surveys
  - Is model designed for children or adults?

Modeling Children's Hand-to-Mouth [Non-Dietary Ingestion] Exposure

$$APDR = ISR \times SA \times EF \times SEF \times ET / BW$$

APDR	=	Acute potential dose rate (mg/kg/day);
ISR	=	indoor surface residue (0.0025 mg/cm^2);
SA	=	skin surface area (20 cm^2/event);
EF	=	event frequency (20 events/hr for acute; 9.5 events/hr for longer term);
SEF	=	saliva extraction fraction (0.5);
ET	=	exposure time (4 hr/day); and
BW	=	body weight (15 kg).

$$APDR = 0.13 \text{ mg/kg/day}$$

Modeling Children's Dermal Exposure

Dermal APDR = ISR x TC x Abs x ET / BW

ISR	=	indoor surface residue (0.0025 mg/cm^2);
ISR	=	indoor surface residue (mg/cm$^{2)}$
	=	AR x FA
AR	=	application rate (lbs/1,000 ft^2);
FA	=	fraction available for dislodging 0.1);
TC	=	transfer coefficient (6,000 cm^2/hr; any time duration);
Abs	=	absorption fraction (0.1);
ET	=	exposure time (4 hr/day); and
BW	=	body weight (15 kg).

Dermal APDR = 0.4 mg/kg/day

Can Exposures Co-Occur?

- Yes; Therefore aggregate assessment appropriate:
- Example: Toddlers:
  - dermal and inhalation exposure in home [using monitoring data and modeling]
  - potential non-dietary ingestion [using modeling]
  - dietary exposure [using monitoring data]: drinking water

Example: Aggregating Children's Exposure

- Objective:
  - Evaluate a 3 yr old child's total exposure to Chemical C from multiple pathways
  - This population has multiple pathways of exposure; conservative estimate
- Resources / Inputs
  - Modeling and monitoring results already presented

Example: Aggregating Children's Exposure

- Model Algorithm/Assumptions
  - Toxicity endpoints the same for all routes of exposure, so absorbed doses can be added
  - Combined inhalation, dermal and hand-to-mouth exposures from indoor application
  - Dietary intake from water
- ADD = Inhalation Dose + Dermal Dose + Non-dietary Dose + Dietary (water) Dose

Characterization of Children's Exposure Assessment

- Description of exposure scenarios
- Information supporting frequency and use
- Transparency in calculating doses
- Methods of route-to-route extrapolation of dose (if needed)
- Degree of uncertainty (or confidence)
- Degree of completeness (other exposure sources not considered)
- Conservatism of exposure estimate
- Quality of exposure estimate for each scenario

Data Gaps

- Community exposures from air and water releases (data are currently being collected)
- Other potential dermal exposures
- Other manufacturing sources
- Sensitive subpopulations